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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/579,071

05/11/2006

Hoon Han

36470-231117

3306

26694

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11/18/2008

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EXAMINER

DAVIS, RUTH A

ART UNIT

PAPER NUMBER

1651

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/579,071	<b>Applicant(s)</b> HAN ET AL.	
	<b>Examiner</b> Ruth A. Davis	<b>Art Unit</b> 1651	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 August 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 1 is objected to because of the following informalities:

Claim 1 recites alphaMEM with the full term recited after in parenthesis. Applicant is required to first recite the full term, followed by the abbreviation in parenthesis.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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4. Claims 1 –5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erices et al. (2000) in view of Nishikawa et al. (US 2004/0235160).

Applicant claims a method for isolating and culturing mesenchymal stem cells from cryopreserved umbilical cord blood, the method comprising thawing the cryopreserved cord blood, adding alphaMEM, centrifuging to harvest monocytes; isolating CD133 cells; subjecting the isolated cells in alphaMEM with SCF, GM-CSF, G-CSF, IL-3 and IL-6. The cord blood is added with a 2-fold volume of alphaMEM, overlapped on Ficol-Hypaque, and centrifuges to harvest monocytes; and the alphaMEM further comprises an antibiotic, antifungal agent, glutamine and FBS.

Erices teaches harvesting and preparing mesenchymal progenitor cells (MSC) (p.238) from umbilical cord blood (Title and Abstract) wherein diluted cord blood cells are separated into low density fractions (overlaid on ficoll-hypaque) to obtain mononuclear cell (monocytes), suspending the cells into a culture medium comprising alpha-MEM, FBS and gentamycin sulfate (antibiotic) (p.235-236).

The reference does not teach the method wherein the blood is first cryopreserved, the cell marker is CD 133, or wherein the culture medium is in the claimed amount (i.e. 2-fold).

However, at the time of the claimed invention, cryopreserved cord blood was well known and used source of cord blood. In addition, the instant marker was a known marker of mesenchymal cells. Regarding the culture medium and amount thereof, it would have been well within the purview of one in the art to optimize the dilution as a matter of routine experimentation and practice.

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Erices does not teach the inclusion of glutamine, cytokine growth factors or anti-fungal agent in their culture medium. However, inclusion of such factors for mesenchymal cell culture was well known in the prior art. In support, Nishikawa teaches methods for isolating and culturing mesenchymal cells, wherein umbilical cord blood is centrifuged and overlaid with Ficoll Hypaque whereby mononuclear cells (or monocytes) are separated thereby (example 6). Cells expressing certain markers are the cultured with a culture medium supplemented with FBS, glutamine, antibiotics, antifungals, SCF, IL-6, IL-3, G-CSF (0076), and optionally GM-CSF (0032). Moreover, at the time of the claimed invention it would have been obvious to one of ordinary skill in the art to practice the claimed invention in light of the combined teachings of Erices, Nishikawa and routine practices in the art.

### ***Double Patenting***

Rejected on the ground of nonstatutory obviousness-type double patenting are withdrawn due to the TD filed and approved on August 15, 2008.

### ***Response to Arguments***

Applicant argues that the references do not teach isolation of MSC, but HSC.

However, in light of the new rejection above, the arguments are not found persuasive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 -3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth A. Davis/  
Primary Examiner, Art Unit 1651

November 14, 2008